### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

ONUR BASER,	
Plaintiff,	Case No. 13-12591
v.	Judge Denise Page Hood Mag. Judge Laurie J. Michelson
U.S. DEPARTMENT OF VETERANS AFFAIRS	
Defendant.	1

RESPONSE TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

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## **COUNTER STATEMENT OF ISSUES PRESENTED**

I. Whether Defendant's Motion for Summary Judgment Should Be Granted?

Plaintiff says, "No"

Defendant says, "Yes"

# CONTROLLING OR MOST APPROPRIATE AUTHORITY FOR RELIEF SOUGHT

ACLU of Mich. v. FBI, 734 F.3d 460 (6th Cir. 2013)

Abraham & Rose, P.L.C. v. United States, 138 F. 3d 1075 (6th Cir. 1998)

Department of the Air Force v. Rose 425 U.S. 352 (1976)

Norwood v. F.A.A. 993 F.2d 570 (6th Cir. 1993)

Rugiero v. United States DOJ, 257 F. 3d 534 (6th Cir. 2001)

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#### **INTRODUCTION**

Plaintiff Dr. Onur Baser is a University of Michigan professor and medical researcher who routinely works with de-identified health data from government sources to perform health care research for publication in educational journals. This research has twin goals of exploring the most effective course of treatment for various medical problems and also of ensuring that government funds are being used to provide the best possible and most cost-effective treatment for patients. In the course of his research, Dr. Baser has on multiple occasions in the past requested and received through the Freedom of Information Act ("FOIA") de-identified health data from Defendant's Veteran's Health Administration ("VHA"). In March of 2013, Dr. Baser submitted two FOIA requests to the VHA seeking the same type of health information that he had previously received for different time periods. This time, however, the VHA denied the request.

On June 13, 2013, Dr. Baser filed a complaint under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Defendant moved for summary judgment based on affidavits from its own employees claiming the requested data could be re-identified when combined with information in publicly available databases. But Defendant's analysis is fundamentally flawed. It ignores both proper de-identification rules under the Health Insurance Portability and Accountability Act ("HIPAA") and the strong public interest in the release of de-identified health records to medical researchers. Defendant has misapplied proper

de-identification standards and proposes a one-size-fits-all approach to de-identification that would effectively eliminate the ability to perform productive research while providing no increased protection for health information. With proper de-identification and input from Dr. Baser on what variables are necessary to his research, useful data that poses an extremely low risk of re-identification can be released. Therefore, not only should Defendant's motion for summary judgment be denied, but this Court should enter summary judgment in Plaintiff's favor as the VHA has not met its burden to justify the claimed FOIA exemptions.

#### FACTUAL BACKGROUND

### A. Defendant failed to produce any responsive data despite its ability to deidentify the data by removing certain variables

At issue in this case are two separate FOIA requests submitted by Dr. Baser to the VHA. He submitted one request on March 15, 2013 (Ex. A) and the second request on March 20, 2013. (Ex. B). The two requests both sought data files maintained by the VHA that detail services and procedures performed to patients at VHA hospitals over a certain period of time. The only difference between the two requests was the time period of data sought.

These requests were not Dr. Baser's first FOIA requests seeking VHA data. Since 2011, Dr. Baser has requested and received the same type of data from the VHA through FOIA. In the past, the VHA worked with Dr. Baser and produced a great deal of data that is identical to the type of data at issue in the FOIA requests

that are the subject of this lawsuit. (Ex. C at  $\P 9$ ).

In 2013, Defendant began to process Dr. Baser's requests as if it would again produce responsive data. Defendant provided Dr. Baser with estimates of costs for production and collected payment for the data sought. While Defendant was not producing the data in a timely manner, Defendant failed to respond with any substantive concerns even though Dr. Baser, either directly or through counsel, contacted Defendant at least a half dozen times to inquire about the status of the FOIA requests. (Doc.1 at ¶¶ 18-23).¹ Once it became apparent that the VHA was not going to produce the data in question, Dr. Baser was forced to file this lawsuit.

#### B. The data requested is for research that is in the public interest

Dr. Baser sought this information on behalf of his company SIMR, Inc. (STATinMED Research). STATinMED and Dr. Baser's primary research focus is on managing health care costs and improving the quality of health care. To fulfill this mission, STATinMED uses commercial insurance as well as government

¹ In this time period, Plaintiff was contacted by a VA doctor who somehow knew about Dr. Baser's FOIA request. The doctor expressed that he believed it was unfair that Dr. Baser could do this research based on data Dr. Baser received through FOIA. (Ex. C, ¶11). The fact that this doctor was aware of Dr. Baser's request is highly suspect. And, the fact that Defendant suddenly stopped providing the same type of data it had previously provided suggests that other motives were in play in the VA's denial. One possible motive is the protection of VHA's own doctors so that they can have access to VHA data for their own research, to the exclusion of non-VHA doctors. Indeed, because Dr. Baser was able to obtain VHA data through FOIA for his research use more quickly than VHA doctors —in some instances—frustrated VA doctors' ability to compete for research and consulting work based on access to this data.

insurance claims data to perform research on the efficacy and efficiency of various medical protocols. (Ex. C,  $\P\P$  7, 10).

Dr. Baser and STATinMED have used the VHA data as part of already-published papers as well as pending research projects. For instance, an article *Prevalence of Diagnosed Opioid Abuse and its Economic Burden in Veterans Health Administration* was published in Pain Practice, 2013. (Ex. C, Att. 1). This research found that opioid use among VHA patients is seven times higher than in non-VHA patients and was able to confirm that if "greater resources and intervention programs are not devoted, economic costs [for the VHA] will continue to increase, as more patients will require treatment for addiction and comorbidities linked to diagnosed opioid abuse." (Ex. C, Att. 1).

Dr. Baser also is involved in an on-going project that tests the efficacy of the VHA's "MOVE" weight management plan. (Ex. C, Att. 1). MOVE! has substantial start-up and administrative costs but could be extremely cost-effective in avoiding more costly health effects later. Using the de-identified data, Dr. Baser can answer questions, such as: Does the VA receive any benefits from this program, and do veterans use fewer health care resources due to the program? (Ex. C, Att. 1).

This is not the limit of what this information could provide. "With its rich database of clinical data and healthcare utilization on a very important segment of our citizens, the Veterans Administration Health Research can provide critical insights that would inform healthcare delivery and decision-making for the benefit

of both veterans and the general public." (Ex. D, ¶ 14). The information creates a treasure trove of data that can help study the efficiency and quality of VHA health care delivery to both make that system more efficient and to provide guidance to other health care providers.

# C. The data at issue is crucial for Dr. Baser's research and can be provided with several key variables redacted in order to ensure deidentification

In order to do this research, Dr. Baser needs the VHA data. There is no dispute that the requested data does not include names or any specific identifying information of patients. Dr. Baser has requested only a series of data sets that can be used to track the treatment a patient has received. Each patient is identified only by a unique VHA identifier that allows a researcher to follow the care a patient has received over time. This identifier does not correlate with any other publicly-available information and is only linked to the patient in the VHA files. What Dr. Baser does is track the care a patient receives over time to evaluate the effectiveness of the medical care the patient received. (Ex. C, ¶ 15). In order to do meaningful medical research, some demographic detail is necessary, but Dr. Baser does not require all the demographic detail in the data and can forego information such as the location of the treatment. He could also forego receiving information on women, who are a much smaller population in the VHA population and thus

pose a higher risk or re-identification. (Ex. C, 16, Ex. E,  $\P$  50).<sup>2</sup> He does, however, need detail about the treatment dates of patients and what treatments they received, as well as some general demographic details to support his medical research.

However, Defendant – primarily through the affidavits of Dr. Lijia Guo, the Deputy Chief Actuary of the VHA's Office of Actuary, and Susan Hickey, the Supervisory Program Analyst for the VHA's National Data Systems ("NDS") – argues that the information sought by Dr. Baser could be used with publicly available information to identify certain individuals. Then, in theory, someone could determine what health conditions and treatments a particular patient received. This conclusion, however, is based on analysis of the data before any rigorous de-identification was done to it (as requested by Dr. Baser). Then, to remedy the supposed problem with re-identification, Defendant improperly applies HIPAA standards and makes extreme assumptions about the risk of re-identification in order to conclude that Dr. Baser's request cannot be honored without compromising patient privacy.

Dr. Guo and Ms. Hickey's explanations of how they were able to find apparent matches in data are not entirely clear. It is not certain either what actual data they were consulting or what searches they performed to find matches.

<sup>&</sup>lt;sup>2</sup> Dr. Baser has provided a complete list of what variables he does and does not need to Dr. Joseph Gardiner; the list is attached as an Attachment 1 to Ex. D. With these variables provided, Dr. Baser can perform the necessary research, and yet, the risk of re-identification remains extremely low. (Ex. D, ¶ 34).

However, it is without a doubt that they were consulting data that included many specific variables (i.e., patient geographic location, gender, etc.) that is not required by Dr. Baser and that can be withheld or grouped to properly de-identify the data and make it safe for reproduction. In particular, as discussed below, the VHA misapplies HIPAA de-identification procedures by failing to provide any individualized inquiry and instead applying a one-size-fits-all approach to de-identification.

The VHA employees' affidavits and reports have been reviewed by two separate independent experts, Dr. Daniel Barth-Jones and Dr. Joseph Gardiner. Dr. Barth-Jones is a nationally-recognized expert in HIPAA de-identification. He is a professor at Columbia and Wayne State University who is widely published in the field of de-identification of medical data. He founded a company that specializes in providing HIPAA Privacy Rule compliant statistical de-identification determinations and statistical disclosure analytic and control solutions for the healthcare industry. The Department of Human Services' most recent guidance document on HIPAA de-identification came out of a workshop where Dr. Barth-Jones was a presenter and specifically cites to his presentation. (Ex. E, ¶¶ 5-14).

Dr. Gardiner is a professor at Michigan State University in the Department of Epidemiology and Biostatistics. He has done extensive research and is widely published on public health issues. In his research, he regularly uses large administrative and clinical databases. He is a Fellow of the American Statistical

Association among other prestigious organizations. (Ex. D, ¶¶ 1-9).

Both Dr. Barth-Jones and Dr. Gardiner reviewed the conclusions of Dr. Guo and Ms. Hickey. Both conclude that the requested data sets, if properly deidentified consistent with the needs of a medical researcher such as Dr. Baser, could be safely provided with only a minimal risk or re-identification. Further, both commented on the failure of Dr. Guo and Ms. Hickey to conduct their re-identification efforts based on properly de-identified data. Ms. Hickey was able to achieve re-identification essentially using non de-identified data.

Dr. Barth-Jones observed that Ms. Hickey's affidavit is "lacking in the necessary details needed to reliably evaluate the total number of purportedly achievable re-identifications being alleged, let alone to provide the Court with sufficient information to plausibly provide any useful quantification regarding the ability of an independent FOIA recipient . . . to replicate these re-identifications." (Ex. E, ¶27). She has only re-identified four people, and, "the available evidence provided results in associated re-identification risk estimates which demonstrate extremely low re-identification risks." (Ex. E, ¶30).

Dr. Guo's affidavit and supporting documentation purports to engage with the science of re-identification and is much broader and highly problematic in that she purports to create a template for how VHA will respond to all FOIA requests for medical data. Her approach is highly flawed. Effectively, Dr. Guo tries to create one series of assumptions to respond to all requests for medical data. In making her de-identification decisions, she chooses to leave in some variables, which, in her view, require that other variables be excluded. But, this one-size-fits-all approach misunderstands proper de-identification. The de-identification risk stems from the interaction of variables. For instance, if you leave in variables such as location, then it increases the risk of re-identification and requires that other variables be omitted. The narrower the geography, the more variables that need to be grouped or eliminated, while the broader the geography, the more variables that can be included while allowing for a low risk of re-identification. (Ex. E, ¶48).

Dr. Guo has made assumptions about what data to leave in that has led her to claim that nearly all other variables must be excluded. However, no effort was made by the VHA to discuss what variables Dr. Baser did or did not need, and thus the assumptions made by Dr. Guo are not fully consistent with what medical researchers generally will need.

Dr. Guo and Ms. Hickey make a number of other errors in evaluating the data, including failing to consider "false positives," where the possible match could be to another person who is not in the health data, ignoring that "re-identification attempts of any substantive scope are very expensive and time-consuming to conduct, require serious computer and mathematical skills, and are only quite rarely successful," ignoring the two independent ways to de-identify data under HIPAA, and deciding not to have a patient identifier even though that is specifically contemplated by HIPAA. (Ex. E, ¶¶ 37-39, 45, 51).

Both Dr. Barth-Jones and Dr. Gardiner concluded that, contrary to Dr. Guo's conclusion, valuable information can be provided to Dr. Baser with only a minimal risk or re-identification. (Ex. E, ¶¶ 51, 54; Ex. D, ¶ 34).

#### ARGUMENT

At its core, the question before this Court is the extent to which the information sought by Dr. Baser could be used to identify the medical conditions and treatment of identifiable individuals. Nobody disputes that the information sought, by itself, is insufficient to identify any particular individual. The VHA, rather, maintains that the information, when combined with publicly available databases, could be used to identify medical information about individual patients. The VHA's statistical and legal analysis, however, are incorrect, and the data, properly de-identified, should be released to Dr. Baser.

## A. The Underlying FOIA Framework

FOIA is a federal statute, 5 U.S.C. § 552, that requires the government to respond to requests for government documents. Documents must be provided "unless one of nine specific exemptions applies." *ACLU of Mich. v. FBI*, 734 F.3d 460, 465 (6<sup>th</sup> Cir. 2013). These exemptions are outlined at 5 U.S.C. § 552(b)(1)—(9). "In accordance with the FOIA's dominant objective of disclosure, these exemptions are to be narrowly construed." *ACLU of Mich. v. FBI*, 734 F.3d at 465.

Whether some information is subject to exclusion is not the end of the inquiry. "[E]ven if a section of a document is determined to be exempt, 'any

Defendant refuses to produce <u>any</u> information sought by Dr. Baser purportedly based on Exemptions 3 and 6 of FOIA, although it relies primarily on Exemption 6. Exemption 6 of the Freedom of Information Act exempts from disclosure, "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." *Arieff v. United States Dep't of Navy*, 712 F.2d 1462, 1466 (D.C. Cir. 1983).

When confronted with a challenge to a withholding of agency records on the basis of this exemption, courts must make a two-step determination de novo: whether the information sought is to be found in personnel, medical or similar files, and if so, whether its release would constitute a "clearly unwarranted invasion of personal privacy."

Id. (internal citation omitted). "An agency's decision to deny a FOIA request is subject to de novo review by a district court." Abraham & Rose, 138 F.3d at 1077. The burden is on the agency to justify its withholding. ACLU of Mich. v. FBI, 734 F.3d at 465.

# B. Defendant overstates the meaning of the "mosaic approach" and ignores that re-identification risk must be greater than "possibilities"

Defendant frames its entire argument around the so-called mosaic approach to FOIA. Specifically, Defendant argues that "a FOIA exemption can apply to

preclude disclosure of information where there is a privacy interest in the information being disclosed because it can be combined with other information to have the practical effect of revealing private information." (Court Doc. 20 at 14-15). Plaintiff acknowledges that the mere anonymous nature of the data requested from the VHA is not sufficient to compel production under FOIA. However, contrary to Defendant's argument, courts limit reliance on outside sources to situations where a non-speculative, legitimate risk of re-identification exists.

The Supreme Court considered the potential for re-identification under FOIA Exemption 6 in *Department of the Air Force v. Rose 4*25 U.S. 352 (1976). In that case, an individual requested under FOIA case summaries for honor and ethics hearings from the Air Force Academy. The Supreme Court held that Exemption 6 did not justify withholding entire records simply because of a risk of potential identification and that Exemption 6 was "directed at threats to privacy interests more palpable than mere possibilities." *Id.*, at 381, fn. 19.

To be sure, redaction cannot eliminate all risks of identifiability, as any human approximation risks some degree of imperfection, and the consequences of exposure of identity can admittedly be severe. But redaction is a familiar technique in other contexts and exemptions to disclosure under the Act were intended to be practical workable concepts.

*Id.*, at p. 381-82 (citations omitted).

The Sixth Circuit followed the Supreme Court's guidance and rejected arguments akin to what Defendant advocates for in this case. In *Norwood v. F.A.A.* 

993 F.2d 570 (6th Cir. 1993), the plaintiffs had requested personnel files for air traffic controllers who had been reinstated in a settlement to a previous strike. The plaintiff did not seek the name, location, social security number or other identifying information of the air-traffic controllers. Nonetheless, the government resisted, arguing that:

Merely withholding the controllers' names is inadequate to protect their identities, since information regarding the facility, region, representative, addresses, etc. can be pieced together into an identifiable set of circumstances. Such piecing together of fragments of information into an identifiable whole is made even more likely by the existence of a closely knit, nationwide network of controllers. Thus, it is only possible to protect the identity of the settling controllers by withholding any and all information that can lead to identification thereof.

993 F.2d at 574 (emphasis added). The Sixth Circuit flatly rejected this "piecing together" argument. "It seems to us that such a view of protecting privacy – excluding from disclosure any and all fragments of information that might assist a diligent researcher in identifying a person – is not supportable." *Id.*<sup>3</sup> *See also, Arieff v. U.S. Dept. of Navy* 712 F.2d 1462, 1467 (D.C. Cir. 1983) ("insofar as the totality of these records is concerned, appellee has established no more than a 'mere possibility' that the medical condition of a particular individual might be disclosed"); *Dayton Newspapers, Inc. v. Dept. of Veteran Affairs* 257 F.Supp.2d 988, 1003-1004 (S.D. Ohio 2003)(granting summary judgment to plaintiff on the

<sup>&</sup>lt;sup>3</sup> Not surprisingly, given *Norwood*, Defendant's string citation of courts applying the "mosaic" approach does not include any cases from courts within the Sixth Circuit.

release of certain information in the face of VA's invocation of Exemption 6 and a "missing link" argument).

These decisions demonstrate that in determining whether disclosure would constitute an unwarranted invasion of privacy – particularly under Exemption 6 – the practical probability of such an invasion must be considered. If there is no meaningful risk that information can be traced to identifiable individuals, there is no unwarranted invasion of personal privacy.

Here, there is no meaningful risk of re-identification if the VHA properly deidentifies this data. As Dr. Barth-Jones testified, attempts to find people in data deidentified to the HIPAA standard "are very expensive and time-consuming to conduct, require serious computer and mathematical skills, are only quite rarely successful and are almost always (when conducted in the real world instead of as scientific experiments) ultimately uncertain as to whether the attempts have actually succeeded." (Ex. E, ¶ 45). Given the data requested, the cost, difficulty to a lay person in properly understanding the data, and amount of specific knowledge needed about a person in order to make an attempt at re-identification all make the possibility of a re-identification remote. Re-identification in this context is well beyond "fragments of information that might assist a diligent researcher in identifying a person" that was deemed "insupportable" as a standard for withholding documents in Norwood.

The Arieff decision is particularly relevant because it also deals with medical

information. In that case, the plaintiff was a journalist who sought the names and amounts of prescription drugs ordered by the Office of Attending Physicians to the United States Congress. This body provided medical care primarily to members of Congress. The district court granted summary judgment for the agency, finding that "disclosure of the records -- given the existence of other fragmented, publicly available information concerning Beneficiaries' health and . . . would enable identification of the medical conditions of particular individuals." Arieff, 721 F.2d at 1466. The D.C. Circuit reversed in an opinion authored by then-Judge Scalia and joined by then-Judge Ginsburg. The Court rejected the "missing link" analysis and held that "even assuming the identifiability of each drug with a particular disease, insofar as the totality of these records is concerned, appellee has established no more than a 'mere possibility' that the medical condition of a particular individual might be disclosed." *Arieff*, 712 F.2d at 1467.

# C. Plaintiff seeks evidence that is de-identified pursuant to commonly-accepted standards, including HIPAA, and since such information can be released, the VHA must release the relevant information

Defendant primarily argues that the de-identified medical information sought by Dr. Baser could be used to re-identify individual people when combined with publicly available sources. But, Defendant misapplies HIPAA in attempting to de-identify the data. HIPAA provides for the provision of de-identified health documents if one of two possible methods of de-identification occurs. Health information is considered de-identified based either on "Expert Determination" or

if potentially identifying information is removed pursuant to HIPAA "Safe Harbor" provisions. The Expert Determination is satisfied when a person with appropriate knowledge "determines the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information." 45 CFR 164.514(1). HIPAA regulations also create a "safe harbor" where if certain identifiers are removed, then the data is considered deidentified. 45 CFR 164.514(2).

In order to deny Dr. Baser's request, Defendant has improperly conflated the two HIPAA processes for de-identification. What Defendant has done is to apply HIPAA safe harbor and then, on top of that, apply an "expert determination" that the information cannot be safely released. HIPAA is clear that either method is appropriate, not that both are required. Defendant's approach eviscerates the "Expert Determination" provision because it first requires full compliance with the "Safe Harbor." This is an erroneous process and unnecessary for proper de-identification of data. Defendant's process

ignores the fact that the Expert Determination method was purposefully proposed by HHS in order to provide an alternative method capable of relaxing the stringent criteria imposed by Safe Harbor on geographic reporting at §164.514(b)(2)(i)(B), or for dates more specific than the year at §164.514(b)(2)(i)(C) and preserving availability of these important information types relative to the analytic needs for such information and the overall context of the combined quasi-identifiers in the data.

(Ex. E,  $\P$  46) (internal citation omitted).

By applying safe harbor first, Defendant also ignores the possibility that Dr. Baser could require less-specific data than is provided for in the safe harbor method. For instance, Dr. Baser does not require the level of geographical detail that is provided in safe harbor. By maintaining the safe harbor geographic areas variables, Defendant's analysis unnecessarily restricts other variables. Compared to the "safe harbor" provision, Dr. Baser needs more specific dates than are allowed but does not need as precise geographic areas as safe harbor allows. An expert determination could "quite likely allow for reporting of much more complete date information by, for example, sacrificing these imposed one size fits all geographic rules if geographic reporting was restricted to higher levels such as Census Regions or National reporting." (Ex. E, ¶ 48). Similar broadening of some variables would also be possible if gender-specific information was not included. (Ex. E, ¶ 49).

HIPAA contemplates that an expert in de-identification, such as Dr. Barth-Jones or Dr. Gardiner, can look at the datasets, understand the issues posed by the relevant population (here, veterans), and make a determination that the information is safe for disclosure. Both of Plaintiffs' experts have concluded that information, once properly de-identified, can safely be provided to Dr. Baser so that he could perform meaningful research. Dr. Barth-Jones concluded that: "the evidence produced by the VA has not appropriately scientifically or statistically supported

any contention that the VA would be unable to respond to this FIOA request for de-identified patient-level data without creating greater than de mininis risks to the privacy interests of the individuals for whom this de-identified data has been requested." (Ex. E, ¶ 54). Dr. Gardiner concluded that limiting the data as offered by Dr. Baser in Ex. A to Dr. Gardiner's declaration would lead to "minimal chance of identification of individuals." (Ex. D, ¶ 34).

Based on these conclusions, which rely on proper application of HIPAA deidentification standards, Defendant must provide information to Dr. Baser. Even if this Court were to find that certain elements of the databases should not be provided, Defendant still must produce responsive records because "even if a section of a document is determined to be exempt, 'any *reasonably* segregable portion of [the] record shall be provided to any person requesting such record after deletion of [the exempt] portions…" *Abraham & Rose, P.L.C. v. United States*, 138 F.3d 1075, 1077 (6<sup>th</sup> Cir. 1998) (quoting 5 U.S.C. § 552(b)).<sup>4</sup>

# D. The Government's affidavits are not entitled to deference, and summary judgment for the government is inappropriate in this case

In a typical FOIA case, the plaintiff does not know what the information sought actually says. Here, however, since the VHA has previously provided this data, Dr. Baser is aware of what variables are at issue and what type of information

<sup>&</sup>lt;sup>4</sup> Attachment 1 to Dr. Gardiner's declaration describes the variables that are actually needed by Dr. Baser and which variables can be removed from the dataset such that it can be safely produced.

could be used to re-identify patients. This distorts the normal process for a FOIA case where the Plaintiff and the Court are forced to rely on affidavits from the Government. Because of this: "Ordinarily, the agency may justify its claims of exemption through detailed affidavits, which are entitled to a presumption of good faith." *Rugiero v. United States DOJ*, 257 F.3d 534, 544 (6<sup>th</sup> Cir. 2001). However, this presumption gives way if "evidence contradicts the government's affidavits or establishes bad faith." *Id*.

Here, there is significant evidence contradicting the governments' affidavits. Two separate experts in de-identification both explain a) that the Agency's position is flawed and b) that the data, when properly de-identified, can be released to Dr. Baser. Thus, this Court does not need the Agency alone to explain what information is sought and why it is being withheld. Moreover, there is also evidence of bad faith here, as communications from VHA doctors to Dr. Baser suggest that the VHA may be withholding this data for anti-competitive purposes. (See FN. 1 at p. 3, *infra*). Based on this evidence, any presumption for the government must dissipate, and instead, the record demonstrates that the government's position is unfounded.

Plaintiff's supporting affidavits detail at length errors that Defendant's

<sup>&</sup>lt;sup>5</sup> It should also be noted that Defendant does not provide affidavits from independent experts but instead provides self-serving testimony from individuals who are VA employees. For this additional reason, these affidavits are not entitled to deference.

experts made in their analysis. In addition to the major conceptual error of conflating the separate "safe harbor" and "Expert Determination" addressed above, the supporting affidavits fail to apply the highest level of statistical de-They have adopted an inflexible one-size-fits-all identification principles. approach to de-identifying health care data that ignores the fluid nature of deidentification, where exclusion of certain variables allows for inclusion of others. Their "re-identifications" are generally based on data that would not be beneficial to health care researchers and are not, as a factual matter, necessary for Dr. Baser. The VHA, by "only utilizing a re-identification risk assessment methodology based on measures of sample uniqueness" has made risk estimates that "are highly likely to be dramatically over-conservative with regard to the actual re-identification risk." The VHA has also ignored the possibility of "false positives" and the impact that has on the actual risk of re-identification. (Ex. E,  $\P\P$  38-39, 46).

## E. Release of VHA treatment data is substantially in the public interest

The issue of whether this information is identifiable is important because it becomes part of the balancing test required in evaluating Exemption 6 of FOIA.

This Court must balance the risk that disclosure will cause "substantial harm" with

<sup>&</sup>lt;sup>6</sup> For instance, if a FOIA recipient were to find an example in the data where the person with a particular birth date and zip code was an exact match for a person they were attempting to re-identify, they have no way of knowing if that is the exact person in the medical records or if there is someone else, who has not received VHA treatment. Even if they have reliable public databases, they have no way of knowing if someone who is not in those databases is the actual match.

the "public interest" in the disclosure being sought. First, if the data sought is limited as requested by Dr. Baser and based on the recommendations of Dr. Barth-Jones and Dr. Gardiner, there is an extremely small risk of "substantial harm." Release of the information poses only a "mere possibility" of re-identification, which is insufficient to constitute substantial harm. *See Department of the Air Force v. Rose*, 425 U.S. 352, 380 n. 19 (1976); *Arieff*, 712 F.2d at 1467.

Even if the Court were to find there was a legitimate risk of re-identification, the speculative harm pales in comparison to the substantial public interest in this data. Plaintiff is seeking detailed information about the care provided by the VHA to veterans. This data can be used to see how the government spends its money on medical care, which allows for research into both the quality of care provided to veterans and whether the care offered is cost-effective.

Defendant's analysis of this prong is fatally flawed. Defendant ignores this clear public interest and asserts that the only relevant interest is a "public benefit in the research and work [Dr. Baser's] company does with the requested datasets." Leaving aside the weight that this also valid public interest should be afforded, it ignores the clear interest in evaluating the efficacy of the VHA's provision of health care to veterans.

Judge Scalia in the *Arieff* opinion specifically noted that similar concerns provide a strong motive for disclosure.

[A]ppellant points to a public interest in knowing, among other things,

the quantities of prescription drugs made available cost-free to Beneficiaries; the extent to which OAP prescribes name-brand drugs as opposed to presumably less costly "generic" drugs; and whether OAP prescribes drugs which the Food and Drug Administration has found to lack evidence of effectiveness for the recommended use . . .[I]t seems to us appellant's position is a relatively strong one. Providing information material for monitoring the Government's activities is the core purpose of the FOIA.

Arieff, 712 F.2d at 1468 (internal citations omitted). Balanced against the very small risk of re-identification posed by the data Plaintiff actually needs, there seems no doubt that the balance tips in Plaintiff's favor. If the ability to evaluate VHA's programs turns on a risk of re-identification substantially lower than a lightning strike, then the information must be disclosed. (Ex. E, ¶ 32).

The public interest expands beyond merely whether the VHA is effectively using its tax dollars to care for our veterans. We are a country in the middle of heated debates about how our citizens get health care. The VHA has a limited population but its effectiveness or lack of effectiveness should be studied to answer fundamental questions about whether the government can or cannot provide cost-effective, quality health care. If the government cannot provide quality, cost-effective health care to its veterans, can it be trusted to provide health care to a broader population?

Likewise, Defendant's position is extremely threatening to academic research in general. FOIA can currently be used to obtain agency records for, among others, investigative reporting and research (historical, academic, statistical,

etc.) not related to the public understanding of the operations or activities of the government. Defendant is taking a highly-dangerous position that any person-level data will not be disclosed. This would serve to quash an enormous amount of productive research in the sciences and social sciences, even where a person could show that the risk of re-identification is non-existent or, at most, extremely small.

# F. Where individuals cannot be reasonably re-identified, exemption 3 also does not apply

Defendant also cursorily raises an argument that Exemption 3 to the FOIA also applies. This exemption allows the government to deny a FOIA request if the matters sought are "specifically exempt from disclosure by statute" and the statute at issue either "(i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld." Defendant alleges that two statutes would be violated by responding to the FOIA, 38 U.S.C. § 5701 and 38 U.S.C. § 7332. These statutes are not applicable first because the risk of re-identification is extremely low and second because the release of deidentified health information sought by Dr. Baser is not what is prohibited by the relevant statutes.

First, Defendant's entire position on Exemption 3 is that because of its argument that individuals are re-identifiable, disclosure would allegedly violate these statutes. As discussed fully above, the risk of re-identification is extremely

small and so statistically improbable that providing this information does not in any way violate the two statutes relied on by Defendant.

Second, the two statutes themselves are silent on the release of de-identified health information. First, 38 U.S.C. § 5701 is a statute that deals with claims for veterans' benefits and prohibits disclosure of records "in the possession of the Department." The statute does not prohibit the disclosure of de-identified health data that could be used with public information to potentially identify a person.

The case relied on by Defendant that called Section 5701 an Exemption 3 statute involved a FOIA request for information that the Government asserted was "included in exempt record systems, internal agency correspondence, private information regarding third parties or confidential information regarding law enforcement matters." *Ashton v. Dep't of Veterans* Affairs, 198 F.3d 233, at \*1 (2d Cir. 1999) (unpublished). There was no discussion in that opinion of the Section 5701 exemption, and certainly defendant was not relying on the "mosaic" approach of combining public and private information to deny disclosure.

The second statute at issue, 38 U.S.C. § 7332(a), provides that "Records of the identity, diagnosis, prognosis, or treatment of any patient" suffering from particular diseases are to remain confidential except for limited exceptions. Again, Plaintiff is not seeking disclosure of "records of the identity, diagnosis, prognosis, or treatment of any patient" that is identifiable. The statute has no prohibition on releasing de-identified health data that has a minimal chance of being re-identified.

The only case relied on by Defendant is a case where health information was specifically sought regarding an individual. The plaintiff sought "copies of medical records regarding John D. Bundy's hospitalization" and subsequent medical treatment. The plaintiff thus was seeking the specific records prohibited by the statute. (Court Doc. 20, Ex. 14 at 1).

In full support of Plaintiff's position, the court rejected the government's arguments under Section 7332 and ordered the information be disclosed. In particular, the statute at issue gives a court authority to order the release of the documents, even where the patient has not given consent if after weighing "the public interest and the need for disclosure against the injury to the patient or subject, to the physician-patient relationship, and to the treatment services" a court were to find "good cause." As discussed above, the public interest in disclosure far outweighs the privacy interest involved even if the records were re-identifiable.

# G. If Summary Judgment is denied to Plaintiff, the case should proceed to discovery and trial

Plaintiff believes that if the request is limited, as described by Dr. Barth-Jones and Dr. Gardiner and by omitting the variables in Attachment 1 to Dr. Gardiner's declaration, then, as a matter of law, the risk of re-identification is so low that, when balanced against the public interest, Defendant must provide the requested information. If this Court were to disagree, or feel there is not yet an appropriate record to grant summary judgment in Plaintiff's favor, this case should

proceed to discovery and then to trial.

This case turns primarily on the issue of whether this data can be identified. This is a factual question. As the D.C. Circuit recognized, analysis of Exemption 6 are "fact-intensive, delicate, and far better suited in the first instance for the ruminations of a single trial judge, expert at finding facts." *Summers v. DOJ*, 140 F.3d 1077 (D.C. Cir. 1998); *see also* Margaret B. Kwoka, *The Freedom of Information Act Trial*, 61 Am. U. L. Rev. 217, 268 (2011). Testimony from Dr. Barth-Jones and Dr. Gardiner has identified, at a minimum, a factual issue that if Plaintiff's request is limited, then the risk of re-identification is effectively *de minimis*. If, after hearing testimony, the Court were to believe Plaintiff's experts, then the Court must find that at least this data be provided in response to the FOIAs. Therefore, summary judgment for Defendant must be denied.<sup>7</sup>

In summary, establishing the risk of re-identification is difficult. It requires

In addition, if this Court is unwilling to grant summary judgment to Plaintiff, Plaintiff respectfully requests further discovery. Specifically, Plaintiff would need an opportunity to depose those VHA employees who provided affidavits to understand a) how Dr. Baser's FOIA requests suddenly came to be denied; b) what assumptions and data they used as part of their re-identification efforts; c) test what variables could be removed to make the risk of re-identification significantly decrease; d) understand what options Defendant considered to fulfill its obligations under FOIA or see if, as appears likely, Defendant reached one position and ignored other alternatives. This additional discovery will allow Plaintiff to demonstrate that releasing data sought by Dr. Baser would pose an extremely low risk of re-identification. Furthermore, Plaintiff wants to test the re-identification process used by Defendant to see what additional information, beyond what is sought through this particular motion, can be provided with little or no risk of re-identification. See generally Salvatore Decl., attached as Ex. F).

experts in the field to explain statistical risks and best practices in order to arrive at

an acceptable rate of risk given the public interest involved. It is insufficient for

the government to hide behind insufficiently detailed, self-serving affidavits from

VHA employees and point at speculative results. Plaintiff strongly believes that by

limiting the request by removing particular variables, summary judgment in his

favor is appropriate. If not, Plaintiff respectfully requests an opportunity to test

Defendant's methodology and conclusions in order to show that Dr. Barth-Jones

and Dr. Gardiner's conclusions are, in fact, correct.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that Defendant's

motion for summary judgment be denied and that instead summary judgment be

entered on behalf of Plaintiff.

Respectfully submitted,

NACHT, ROUMEL, SALVATORE,

BLANCHARD & WALKER, P.C.

Dated: January 21, 2014

/s/ Jennifer B. Salvatore

Jennifer B. Salvatore (P66640)

Attorney for Plaintiff

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#### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

ONU	JR	$\mathbf{B}$	$\lambda S$	ER	

Plaintiff,

Case No. 13-12591

v.

Judge Denise Page Hood Mag. Judge Laurie J. Michelson

U.S. DEPARTMENT OF VETERANS AFFAIRS, et al,

Defendants.		

#### **CERTIFICATE OF SERVICE**

I hereby certify that on **January 21, 2014**, I electronically filed the foregoing with the <u>United States District Court</u> using the ECF system, and I further certify that I mailed a copy to the non-ECF participant(s).

s/ Teresa N. Tallman Paralegal